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**B. 510(k) SUMMARY (as required by 21 CFR 807.92)****S4 Spinal System**

January 18, 2006

**COMPANY:** Aesculap<sup>®</sup>, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 2916714

**CONTACT:** Lisa M. Boyle  
800-258-1946 (phone)  
610-791-6882 (fax)  
[lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com) (email)

**TRADE NAME:** S4

**COMMON NAME:** S4 Spinal System

**CLASSIFICATION NAME:** Pedicle screw spinal system  
Spinal interlaminar fixation orthosis

**REGULATION NUMBER:** 888.3070 and 888.3050

**PRODUCT CODE:** MNI and KWP

**SUBSTANTIAL EQUIVALENCE**

Aesculap<sup>®</sup>, Inc. believes that the S4 Spinal System additions are substantially equivalent to the existing components of the Aesculap's S4 Spinal System (K050979).

**DEVICE DESCRIPTION**

The S4 Spinal System consists of 3.5mm rods in 6 lengths, thin and thick lamina hooks, 3.5 and 4.0mm polyaxial screws of various lengths and a cross connector. The S4 Spinal System is manufactured from Titanium forged alloy Ti6Al4V.

**INDICATIONS FOR USE**

When intended to promote fusion of the cervical spine and the thoracic spine (C1 – T3), the S4 Spinal System is intended for the following;

- DDD (Neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

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The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 – T3) spine.

The use of the polyaxial screws is limited to placement in T1 – T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The new components of the S4 Spinal System are offered in similar in shapes and sizes as the predicate devices. All the components are manufactured from Titanium Alloy, which is the same material as the predicate devices.

**PERFORMANCE DATA**

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where applicable.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 3 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Lisa Boyle  
Regulatory Affairs Associate II  
Aesculap, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034

Re: K060152

Trade/Device Name: S4 Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNI, KWP  
Dated: January 18, 2006  
Received: January 26, 2006

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
for Mark N. Melkerson  
Acting Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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**A. INDICATIONS FOR USE STATEMENT**510(k) Number: K060152Device Name: **S4 Spinal System****Indications for Use:**

When intended to promote fusion of the cervical spine and the thoracic spine (C1 – T3), the S4 Spinal System is intended for the following;

- DDD (Neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

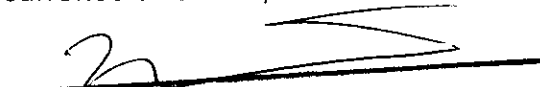
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 – T3) spine.

The use of the polyaxial screws is limited to placement in T1 – T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

Prescription Use     X     and/or Over-the-Counter Use                       
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K060152

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